The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte VASSILIKI A. BOUSSIOTIS and LEE M. NADLER

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Appeal No. 1999-1403
Application 08/270,152

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Before STONER, Chief Administrative Patent Judge, HARKCOM, Vice Chief Administrative Patent Judge, and WILLIAM F. SMITH, Administrative Patent Judge.

WILLIAM F. SMITH, Administrative Patent Judge.

REMAND TO THE EXAMINER

Our consideration of the record leads us to conclude that this case is not in condition for a decision on appeal. Accordingly, we remand the application to the examiner to consider the following issues and to take appropriate action.

1. Petition under 37 CFR § 1.181

Concurrent with the Appeal Brief in this case, appellants filed a petition under 37 CFR § 1.181 seeking to withdraw the finality of the final rejection mailed by the examiner on December 24, 1996 (Paper No. 15). According to the Manual of Patent

Examining Procedure (MPEP) § 1002.02(c)(3), such petitions are decided by the Technology Center Director. The record does not indicate that the Director of Technology Center 1600 has considered appellants' petition. Rather, the examiner states at page 1 of the Examiner's Answer:

> Appellant's [sic] Petition Under 37 CFR 1.181, filed12/15/97 (Paper No. 31) is acknowledged. Upon reconsideration and in the interest of compact prosecution, appellant's [sic] amendment, filed 6/2/97 (Paper No. 25), adding claims 62-67, has been entered.

This paragraph is not understood since the petition of record was not "filed" on December 15, 1997, nor is it entered into the record as Paper No. 31. The record copy of the petition was received by the United States Patent and Trademark Office (USPTO) on December 22, 1997 and bears a certificate of first class mailing dated December 16, 1997. The petition has been entered in the "Contents" section of the file as Paper No. 21. Furthermore, we find no record of an amendment filed June 2, 1997 as Paper No. 25. There is an amendment received by facsimile transmission at the USPTO on June 24, 1997 entered as Paper No. 17.

However, at page 2 of the Examiner's Answer the examiner states:

> Appellant [sic] Petition under 37 CFR 1.181 To Withdraw Finality of Rejection, filed 12/22/97 (Paper No. 21) is acknowledged. Appellant's [sic] arguments have been fully considered but are not found convincing. Appellant's [sic] arguments appear to indicate to that the first ground or rejection under 35 USC 112, first paragraph, was drawn to enablement of clinical applications of the claimed methods, while the second ground of rejection was based on the predictability of success of the in vitro and in vivo therapeutic methods encompassed by the instant claims. In contrast to appellant's [sic] assertions of different grounds of rejection and the deprivation of an opportunity to respond; the

> rejection of record under 35 USC 112, first paragraph, have addressed the predictability of the claimed methods based on the instant disclosure as they apply to enablement and scope issues under the Forman Factors. Appellant's [sic] arguments are not found persuasive.

Upon return of the application, the examiner is to clarify the record as to how many petitions have been filed in this case. If the only petition of record is that received by the USPTO on December 22, 1997, it does not appear that that petition has been considered by the appropriate USPTO official. Thus, upon return of the application, the examiner should see to it that the Group Director of Technical Center 1600 has considered the petition.

2. Statement of Rejection

The statement of the rejection which begins at page 3 of the Examiner's Answer does not refer to specific claims. Rather, it states that the rejection under 35 U.S.C. § 112, first paragraph is "applicable to the appealed claims." By this, we believe the examiner is rejecting claims 48, 50, 55 through 61 and 98 as it is believed that these claims along with claim 97 which the examiner has indicated as directed to allowable subject matter are the only claims left pending in this application.

Be that as it may, the examiner's statement of the rejection relies upon 5 references identified as Basker, Boussiotis (1994), Boussiotis (1995), Blue Stone Immunity and Russell. When this rejection was first made in the first Office action on the merits (Paper No. 11), the examiner only relied upon Boussiotis (1994) and Russell. In

maintaining this rejection in the final Office action (Paper No. 15), the examiner stated at page 3 thereof that the rejection is "as set forth in the previous Office Action (Paper No. 11)."

In the Advisory Action mailed July 16, 1997 (Paper No. 18), the examiner cited Boussiotis (1995) and Blue Stone Immunity but did not reopen prosecution and properly incorporate these references in his statement of rejection.

The examiner's reliance upon Basker, Boussiotis (1995) and Blue Stone Immunity in support of the rejection in the Examiner's Answer is subject to question as it appears that the examiner has made a new ground of rejection. As indicated, Boussiotis (1995) and Blue Stone Immunity were first cited in an Advisory Action but were not incorporated into a formal statement of a rejection at that point in time. It does not appear that Basker had been relied upon by the examiner in support of the rejection prior to the entry of the Examiner's Answer. As of October 10, 1997, examiners are only permitted to enter a new ground of rejection in an Examiner's Answer upon very limited circumstances, which circumstances do not appear to be present here.

Apart from the "newness" of the examiner's rejection in the Examiner's Answer, the examiner's position on appeal would be difficult to review for another reason. The examiner acknowledges at page 6 of the Examiner's Answer that factors to be taken into account in determining enablement of the claimed invention are set forth in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. Int. 1986). However, in stating the rejection on

pages 3-5 of the Examiner's Answer, the examiner does not present a fact-based analysis of these factors.

Upon return of the application, the examiner should consider what the propriety and substance of the statement of the rejection as it is set forth in the Examiner's Answer. If the statement of the rejection does amount to a new ground of rejection the examiner should take appropriate action. In any event, it would be helpful to both appellants and the board if the examiner would restate the rejection and in an appropriate Office action explicitly taking into account the Forman factors in a fact-based manner. We refer the examiner to the court's opinion in Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999) for a model of how to express an enablement rejection taking into account the Forman factors in a fact-based manner.

3. Reply Brief

Appellants filed a Reply Brief received by the USPTO on May 26, 1998. Therein, the appellants question the propriety of the examiner relying upon documents published after the effective filing date of this application in support of the enablement rejection. In addition, appellant relies upon documents in support of their position which are attached to the Reply Brief as Exhibits A and B. The examiner issued a "Communication" on July 24, 1998 which states that the Reply Brief has been entered. However, the examiner does not state whether Exhibits A and B were also entered.

37 CFR § 1.195 states:

> Affidavits, declarations, or exhibits submitted after the case has been

> appealed will not be admitted without a showing of good and sufficient reasons why they were not earlier presented.

It does not appear that appellants made a showing under 37 CFR § 1.195 in conjunction with their filing of Exhibits A and B with the Reply Brief. As indicated, the examiner has made no independent determination as to whether the Exhibits are entered or not.

Upon return of the application, the examiner should review the Reply Brief and determine whether Exhibits A and B were properly filed under 37 CFR § 1.195. If the examiner determines that the exhibits were not timely presented, he should notify appellants of that determination so that they can determine how to proceed. However, it may be that from consideration of appellants petition under 37 CFR § 1.181 and the above stated need for the examiner to, at the least, restate the rejection of record, events will have overtaken this issue in that if prosecution is reopened by way of the petition or by way of the examiner restating the rejection the examiner will of necessity need to consider appellants' position in the Reply Brief as well as Exhibits A and B.

4. Appeal Conference

It does not appear from the record that an appeal conference was held prior to forwarding this case to the board. We believe it would be helpful if an appeal conference were to be convened upon return of the application to the examiner to discuss the issues raised in this appeal.

5. Future Proceedings

We state that we are not authorizing a Supplemental Examiner's Answer under 37 CFR § 1.193(b)(1).

This application, by virtue of its "special" status, requires an immediate action. MPEP § 708.01 (7th ed., rev. 1, February 2000). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REMANDED

Bruce H. Stoner, Jr., Chief
Administrative Patent Judge

Gary V. Harkcom, Vice Chief
Administrative Patent Judge

William F. Smith
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

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